PRO-Soft QA-40M/45
User Manual

Defibrillator-/ Transcutaneous
Pacemaker Analyzer

METRON

P1115035

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METRON:

USA
1345 Monroe NW, Suite 255A
Grand Rapids, MI 49505
Phone: (+1) 888 863-8766
Fax: (+1) 616 454-3350
E-mail: *metronus@aol.com*

FRANCE
30, rue Paul Claudel
91000 Evry, France
Phone: (+33) 1 6078 8899
Fax: (+33) 1 6078 6839
E-mail: *metronfrance@infonie.fr*

NORWAY
Travbaneveien 1
N-7044 Trondheim, Norway
Phone: (+47) 7382 8500
Fax: (+47) 7391 7009
E-mail: *support@metron.no*

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Manual Revision Record

This record page is for recording revisions to your *PRO-Soft QA-40M/45 User Manual* that have been published by METRON or its authorized representatives. We recommend that only the management or facility representative authorized to process changes and revisions to publications:

- make the pen changes or insert the revised pages;
- ensure that obsolete pages are withdrawn and either disposed of immediately, or marked as superseded and placed in a superseded document file, and;
- enter the information below reflecting that the revisions have been entered.

Rev No	Date Entered	Reason	Signature of Person Entering Change
0	-	Initial Release	

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1. About PRO-Soft QA-40M/45

1.1 Introduction

The QA-40M and QA-45 Analyzers are precision instruments for testing defibrillators and, additionally with the QA-45, transcutaneous pacemakers. They are designed to be used by trained technicians.

The defibrillator function of the QA-40M and QA-45 measures the energy output, and ensures that the defibrillator complies with specified requirements. QA-40M and QA-45 have built-in load resistances of 50 ohms, which roughly correspond to the impedance of the human body. The defibrillator pads are placed on the analyzers' contact plates. Thus, the defibrillator is connected through the load resistance. When the defibrillator is discharged, the analyzers calculate and display the energy delivered.

In the pacer function the QA-45 tests all types of transthoracic pacemakers. The testing is menu driven, and simple to operate. QA-45 measures and displays a pulse's amplitude, rate, energy and width. It also conducts demand sensitivity tests, measuring and displaying refractory periods, and immunity tests, which determine the pacemaker's susceptibility to 50/60 Hz interference.

Testing with the QA-40M/45 is usually a matter of setting up the preferred simulation parameters. Using PRO-Soft QA-40M/45 simplifies the process by providing an all Windows-based environment through which simulation parameters are created by the user and sent to the QA-40M/45 unit.

1.2 PRO-Soft QA-40M/45

PRO-Soft QA-40M/45 has two testing methods: manual or sequence. The manual method allows you to set up test parameters quickly, and run one of the following stand alone tests. There are no restrictions on the parameters used.

Defibrillator Discharge Test	ECG Performance Test
Shock Advisory Algorithm Test	Pacemaker Accuracy Test
Pacemaker Sensitivity Test	Pacemaker Refractory Period Test

Test results are entered on the screen during testing. At the conclusion of testing the user may print a report, store the tests and results on disk, or both.

Combinations of tests can be created and stored as "sequences." PRO-Soft QA-40M/45 maintains a library of these sequences. In this way the user can store and retrieve sequences that are appropriate for the kind of equipment being tested. Sequences can then be used independently, or can be attached to a checklist, written procedure, and equipment data in the form of a test "protocol." The equipment

data can be entered manually into the protocol, or it may be retrieved by PRO-Soft from the QA-MAP program, or other equipment files. Protocols with test results can be printed, or stored on disk. Also, the results of testing can be sent to QA-MAP, or other equipment maintenance management program, to close a work order and update the defibrillator/transcutaneous pacemaker's service history.

An additional feature of PRO-Soft QA-40M/45 is its ability to make QA-40/45 serve as a training aid device for medical staff personnel who operate defibrillators in the course of their duties. Several ECG waveform emergency sequences are incorporated into the program. These sequences interact with incoming defibrillator pulses, simulating various patient cardiovascular conditions.

1.3 About your Manual

This manual is designed to assist you in the basic procedures for creating test protocols with PRO-Soft QA-40M/45. It also covers all features resident in the full PRO-Soft program. Familiarity with Microsoft Windows and its features is assumed. If you are unfamiliar with it, we recommend that you use your *Microsoft Windows User's Guide* along with this manual.

This manual contains the following standardized text formatting conventions:

This	Represents
Bold title case	Menu items and control buttons that can be selected to perform operations. The underline (_) represents the shortcut key. For example, "**Select File**, **Save**" instructs you to press "Alt+F," then press "Alt+S." The comma (,) between selections indicates that both selections are to be made in sequence.
< braces >	Text information specified and entered by the user.
CAPITALS	File names and paths. For example, "QAMDAT.50"
	The menu under discussion

1.4 Updating PRO-Soft Program Files

NOTE
When installing upgrades, backup or copy the original program files to ensure that data you desire to retain is not overwritten.

Occasionally, updated versions of PRO-Soft QA-40M/45 program files are posted on METRON's Web Site (http://www.metron-biomed. com). These can be downloaded through file transfer procedures. Registered users should contact their local METRON representative for more information regarding updating.

2. Getting Started

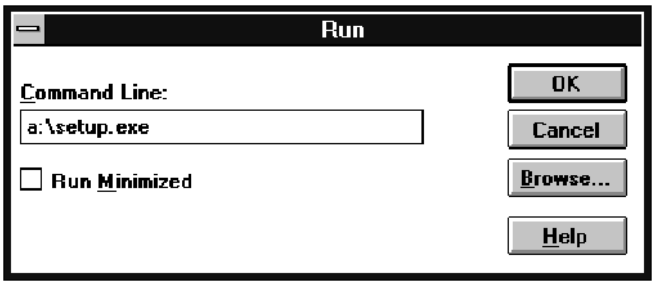
2.1 System Requirements

The following are the minimum requirements for installation:

- IBM PC/XT-compatible machine, 80486 SX 25 MHZ or higher.
- A 3.5" floppy drive.
- An EGA, VGA, 8514, Hercules or compatible display (recommended: VGA).
- 8 MB of RAM.
- 1 MB of unoccupied hard disk space, plus 3 MB of free space on the drive contained the WINDOWS:\SYSTEM directory.
- Microsoft Windows version 3.11 or later version.
- Metron QA-40M/45.
- RS-232 cable (null modem/data transfer configured).
- Printer for reports. (MS-Windows compatible)

2.2 Installing PRO-Soft

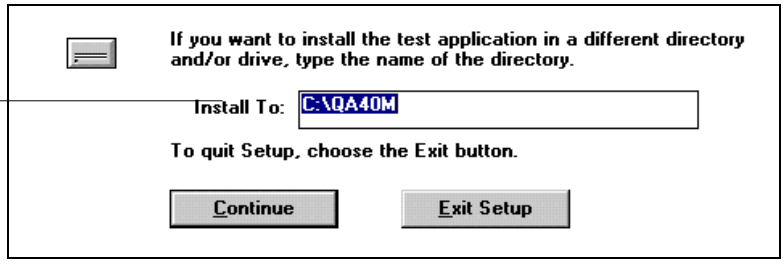
1. Start Windows.
2. Insert PRO-Soft QA-40M/45 install disk # 1 into drive A (or B).
3. Select **Run** from the File Menu in the Windows Program Manager. (In Win 95, click the **Start** button and then select **Run**.)



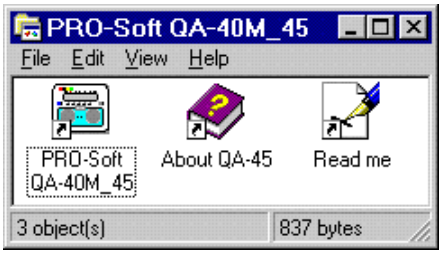
4. Type <drive:\setup>. Then, click the **OK** button. If you are installing PRO-Soft QA-40M/45 from a server or shared directory, type the full path plus setup**.**

5. When setup starts, the following dialog box will appear. Type in the desired drive and directory for PRO-Soft QA-40M/45, then click the **Continue** button.

If you are installing PRO-Soft QA-40M/45 for the first time, we recommend using the default drive, directory, and program group (C:\QA-40M/45)


If you want to install the test application in a different directory and/or drive, type the name of the directory.
Install To:
C:\QA40M
To quit Setup, choose the Exit button.
Continue
Exit Setup

6. After setup is completed, a program group will be created in the Windows Program Manager called "PRO-Soft QA-40M/45," or another name you provided during installation.



7. Remove the last disk and store the install disks in a safe place.

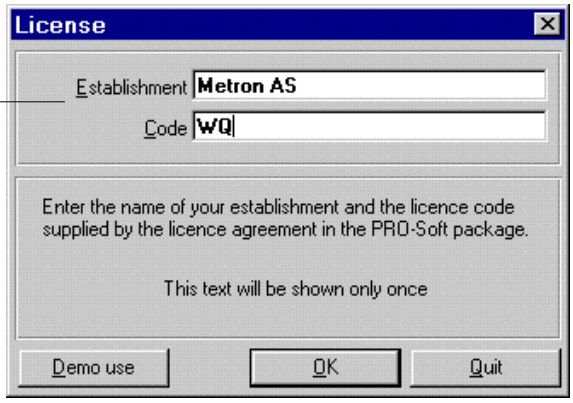
2.3 Initial Startup

The first time that PRO-Soft QA-40M/45 is run, information has to be entered, and the program configured for further use.

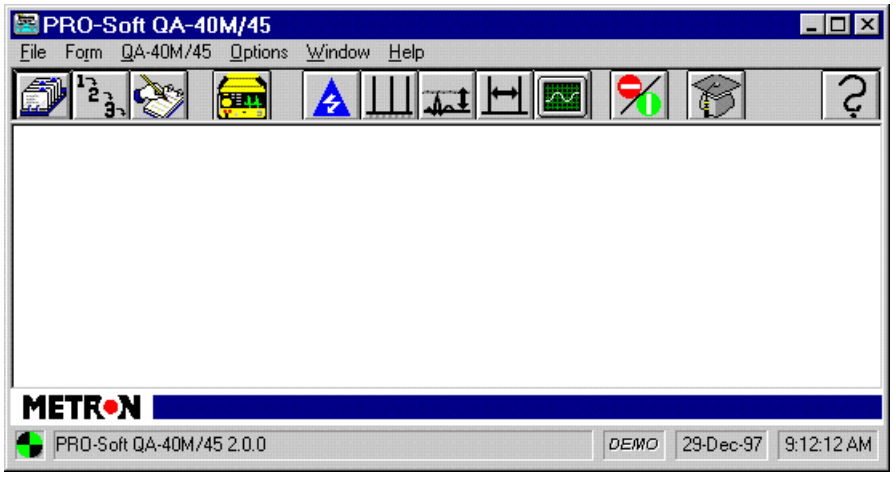
1. To start the program, double-click on the QA-40M/45 icon.

2. The following dialog box will appear. Enter the **Establishment** <license holder name>, and the **Code** <alphanumeric license number> exactly as written on the license agreement supplied:

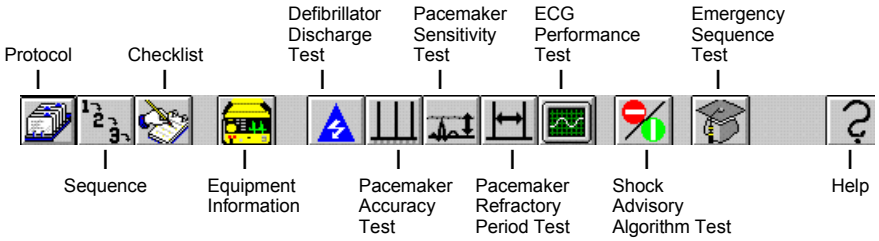
Be careful to enter the name and code exactly as written on the license agreement.



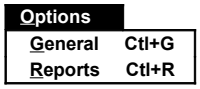
3. When you click the **OK** button the PRO-Soft QA-40M/45 main application window is displayed:



The Main Application Window contains menus as well as an icon bar. This bar enables the user to advance quickly to the following program operations through pressing the appropriate icon:

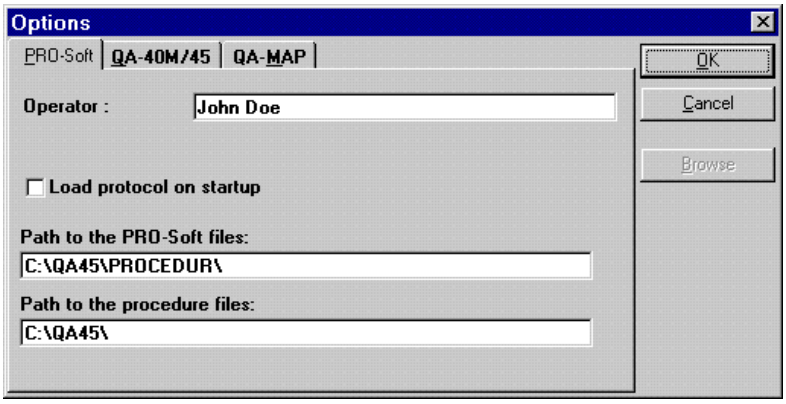


2.4 Option Settings



To configure program parameters click the **Option** Menu. Two further selections appear: **General**, which sets program pathing parameters, and **Reports**, which sets standardized report headers .

1. **General.** When selected, the following dialog box appears:



In the topmost section of this box there are three tabs: **PRO-Soft**, **QA-40M/45**, and **QA-MAP**. By clicking one of these tabs, its corresponding card will be displayed, containing the settings available for the item described on the tab.

After editing the option settings press **OK** to save changes, or **Cancel** to discard them. When a <Path> text box is highlighted the **Browse** button will also be available and, by pressing this button, a file window will be displayed where you can select the appropriate path.

a. **PRO-Soft Tab**. This tab provides basic identification of the operator of the test equipment, as well as pathing directions for the PRO-Soft program in order for it to function. The configuration parameters and their descriptions are:

Operator:	The person executing the tests.
Load protocol at startup:	This option, when checked, automatically advances the program and opens to a blank protocol window at startup.
Path in the PRO-Soft files:	Path to the QA-40M/45 database files.
Path to procedure files:	Default path to the files where the test procedures are stored.

The operator, automatic loading, and pathing settings, once made, become the default settings. To change the defaults, enter new operator and pathing settings or, in the case of automatic protocol loading, uncheck the box. Then, save by pressing **OK**.

b. **QA-40M/45 Tab**. This tab is used to enter the serial number of the QA-40M/45 utilized for testing, and to set the communications port (COM1-4) to be utilized for initiating the QA-40M/45 remote setting at start-up. Once entered, these become the default settings. To change the defaults,

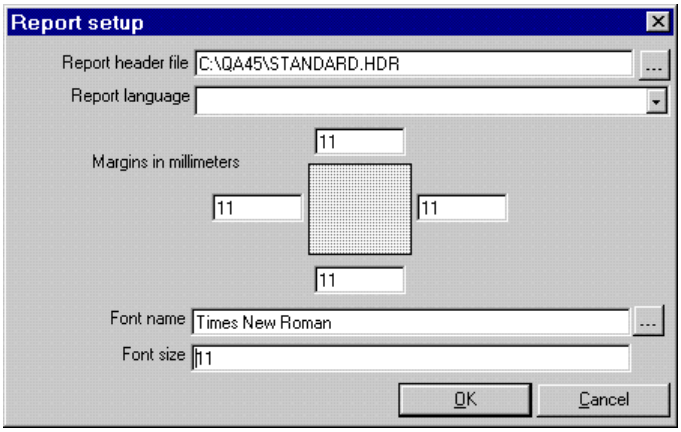
enter a new serial number or enter a new COM Port, and save by pressing **OK**.

c. **QA-MAP Tab**. Most QA-MAP interaction control settings included in the PRO-Soft options may be changed during the execution of the PRO-Soft QA-MAP Program[1]. However, the following default settings are only available through the PRO-Soft QA-40M/45 options menu:

Path:	Path to the QA-MAP file QAMDAT.MDB.
List equipment codes when retrieving data:	Controls whether the equipment list window or the equipment code text box window opens in the retrieval operation.
Retrieve from QA-MAP: **- Equipment data** **- Sequence** **- Procedure**	Sets the defaults as to the types of information extracted from QA-MAP.

Once entered, these become the default settings. To change them, enter new setting and save by pressing **OK**.

2. **Report.** When selected, the following dialog box appears:



Report header title:	The path and filename of the header to be used on all reports.
Report language:	This text box is blank, as default is automatically English. If other languages are desired, contact your METRON representative for the appropriate files.
Margins in millimeters:	Path to the QA-40M/45 database files.
Font name:	Report default font.
Font size:	Report default font size.

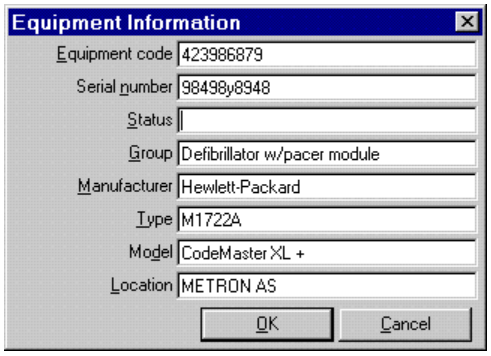
The heading layout of test reports can be customized by editing the file 'STANDARD.HDR' in the PRO-Soft directory with any text editor (e.g., MS Windows Notpad). See Appendix A for further guidance.

[1] Available separately from your Metron Representative.

2.5 Printing Test Results

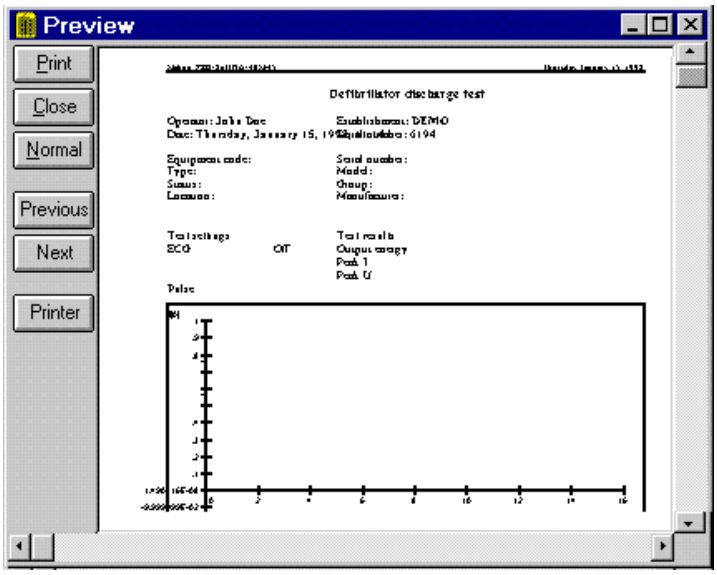
1. Test results are printed by selecting the **Print** button on the test result window.

   If this is the first test result for a manual test session you will be prompted to fill in a Equipment Information Form (*see below*).



   Each time a test is run thereafter, the printed result is buffered. A complete report will be sent to the printer when the test window is closed.

2. After selecting **Print** (or after entering the Equipment Information Form and selecting **OK**) the following window appears. This is for prepublication review, and is in a WYSIWYG format.



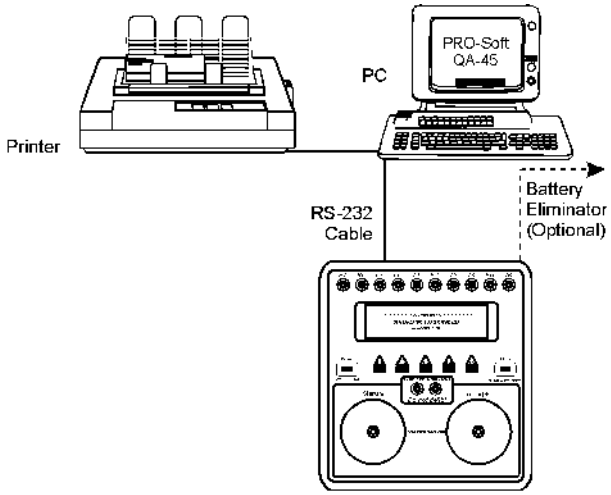
   Window controls enable you to enlarge the results, and navigate from one page to the next. When review is complete, press the **Print** button.

3. Testing Setup

Communication between the PRO-Soft QA-40M/45 and the QA-40M/45 is based upon an RS-232C interface, that is standard on most modern personal computers. The operation is essentially a "master-slave" configuration, whereby the computer operates the QA-40M/45.

3.1 Equipment Setup

Attach an RS-232 (null modem/data transfer configured) cable to the 9-pin D-sub outlet port located at the rear of the QA-45. Do not attach the printer cable to the QA-45. *See below*.



NOTE
Some RS-232C cables are missing the connection between the seventh and the eighth wires in the cable. The cable may still be called NULL-modem, but it will not work with the QA-40M/45.

3.2 Power

1. **Main On/Off Switch.** QA-45 should remain off for at least 5 seconds before switching on again, in order to allow the test circuits to discharge fully.
2. **Low Battery Power.** If battery power falls below 6.9 volts (± 0.3 volts), the display will show 'Change battery, and reset system'. This means that the battery should either be replaced or the instrument should be connected to a battery eliminator. The main switch has to be switched off and then on again in order to use the instrument.
3. **Changing Batteries.** Open the compartments in the base of the instrument, replace the old batteries with new ones, and close the compartment covers. Use 9 volt alkaline batteries (Duracell MN1604 or similar).

NOTE
Do not use mercury, air or carbon-zinc batteries.

4. **Battery Eliminator**

   METRON's AC Adapter plug-in power supply transformer allows you to use the QA-40M/45 anywhere a standard electrical outlet is available. To attach the adapter insert its small connector into the micro jack labeled "Batt. Elim. 9V DC" on the right rear of the unit. Plug the large connector into a standard electrical outlet.

NOTE
Remove the batteries and disconnect the AC Adapter if you do not intend to use the QA-40M/45 for an extended period of time.

3.3 Internal Paddles

To be able to test defibrillators with internal paddles, an internal paddle adapter has to be used. These contacts have a banana plug that is attached to the standard paddle contact, and which is protected by a plastic insulation washer.

3.4 Special Contacts

Certain defibrillators (automatic models and those with pacer options) have special contacts that are fastened to the electrodes attached to the patient. Metron AS has special accessory adapters to suit the majority of these defibrillators. They are more or less the same as the internal pad adapter except that they have a special adapter on the top, which matches the contact on the defibrillator.

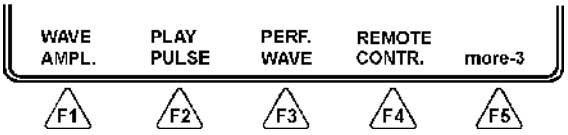
Defibrillator paddle adapter (specify defibrillator type):	(P/N 13410)
Pacemaker external load cable (specify type pacemaker type):	(P/N 13415)

3.5 Initializing Remoting - Defibrillator Mode

1. Before initiating remote control, ensure that the:
   - RS-232C cable is securely connected to the communication ports on the QA-40M/45 and your computer.
   - Proper communications port has been assigned.
   - 'Mode' Switch is in the 'HIGH' or 'LOW' position.

High	For Normal adult testing
Low	For low energy testing, where energy does not exceed 50 joules, and peak voltage does not exceed 1200 volts.

   - Low or high level ECG connectors are connected to the ten 4 mm AHA color-coded safety terminals, or standard phone jack, as appropriate.
2. With the QA-40M/45 switched **ON**, advance to the Second Main Menu Bar by pressing **more-2 (F5)**:

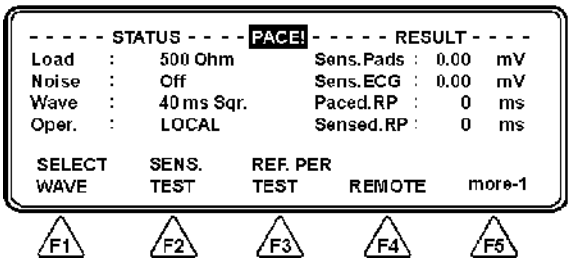


Press **REMOTE CONTR. (F4)** to initiate remote control.

3. Communication will be established when testing or downloading of presets start. A rolling ball, located in the lower left corner of the main application window (*see below*), indicates that communication between the computer and the QA-40M/45 is active.

3.6 Initializing Remoting - Pacemaker Mode (QA-45 only)

1. Before initiating remote control, ensure that the:
   - RS-232C cable is securely connected to the communication ports on the QA-40M/45 and your computer.
   - Proper communications port has been assigned.
   - Mode Switch is in the ‘PACE’ position.
   - Pacemaker output cables are connected to either the 'Pacer Input Variable Load' or 'Pacer Input Fixed Load' on QA-45.
   - Pacemaker is in ‘DEMAND’ mode (if immunity testing).
2. With the QA-45 switched **ON**, advance to the Second Main Menu Bar by pressing **more-2 (F5)**:


- - - - - STATUS - - - - PACE! - - - - - RESULT - - - -
Load : 500 Ohm Sens.Pads : 0.00 mV
Noise : Off Sens.ECG : 0.00 mV
Wave : 40 ms Sqr. Paced.RP : 0 ms
Oper. : LOCAL Sensed.RP : 0 ms
SELECT WAVE
SENS. TEST
REF. PER TEST
REMOTE
more-1
F1
F2
F3
F4
F5

Press **REMOTE CONTR. (F4)** to initiate remote control.

3. Communication will be established when testing or downloading of presets start. A rolling ball, located in the lower left corner of the main application window (*see below*), indicates that communication between the computer and the QA-45 is active.

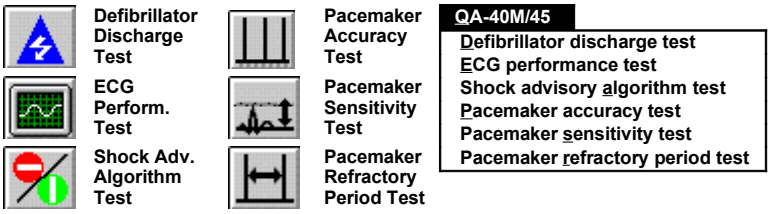
4. Manual Testing

The **Manual** method allows you to set up test parameters quickly, and run one of the following stand alone tests:

Defibrillator Discharge Test	ECG Performance Test
Shock Advisory Algorithm Test	Pacemaker Accuracy Test
Pacemaker Sensitivity Test	Pacemaker Refractory Period Test

There are no restrictions on the parameters used. However, only the QA-45 does both defibrillator and transcutaneous pacemaker testing. The QA-40M is restricted to defibrillator testing only.

Manual tests can be activated in two ways. One is to select the appropriate icon from the icon menu bar in the Main Application Window. *(The icons below are those which activate the tests.)* The other method is to select **QA-45** from the PRO-Soft QA-40M/45 Main Menu, and the Manual Test Menu appears. *(See the menu below.)*



4.1 Defibrillator Discharge (Energy) Test

1. **General**. QA-40M/45 measure the energy output, and ensure that the defibrillator complies with specified requirements. They have a built-in load resistance of 50 ohms, which roughly corresponds to the impedance of the human body. The defibrillator pads are placed on the QA-40M/45 contact plates, thus ensuring that the defibrillator is connected through the load resistance. When the defibrillator is discharged, PRO-Soft calculates and displays the energy delivered.
   Defibrillator energy is defined as an integral of the moment of the discharged energy from the defibrillator. The energy is equal to the square of the voltage, divided by the load resistance.

   $E = \int p\,dt = \int V^2 / R\,dt = \int V^2\,dt / R$

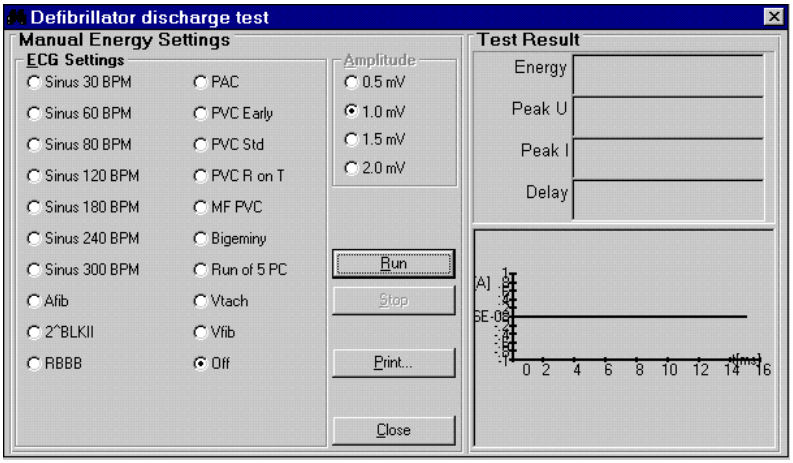
   QA-40M/45 measures and records the voltage pulse every 100 µs, 1000 times, for a total time of 100 ms. The squares of the voltages are then summed, multiplied by 100 µs, and divided by the load resistance, 50 ohms.

   $$E = \sum_{0}^{1000} (V^2) \bullet dt / R = \sum_{0}^{1000} (V^2) \bullet 100\ \mu s / 50\ ohms$$

2. **Test Procedure.**
   a. Initiate remoting. *(See chapter 3 for more information)*

b. Set the defibrillator to 'SYNCHRONIZED' mode, if desired. If set, there must be an ECG wave and amplitude to simulate before testing begins. While the test is activated, the waveform and amplitude cannot be changed.

c. Press the **Defibrillator Discharge Test** icon button or select **QA-45, Defibrillator discharge test** from the PRO-Soft QA-40M/45 Main Menu, and the following appears.



d. In the **Manual Energy Settings** field, select the desired :

ECG Settings PRO-Soft QA-40M/45 includes the following ECG wave selection for cardioversion tests, or for the testing of ECG monitors:

Normal Sine Rates: 30, 60, 80, 120, 180, 240, 300 BPM.

ECG arrhythmia types are as follows:

Afib	Atrial Fibrillation
2^BLKII	Second degree A-V block
RBBB	Right Bundle Branch Block
PAC	Premature Atrial Contraction
PVC Early	Early PVC
PVC Std	PVC
PVC R on T	R on T PVC
MF PVC	Multifocal PVC
Bigeminy	Bigeminy
Run of 5 PC	Bigeminy Run of 5 PVCs
Vtach	Ventricular Tachycardia
Vfib	Ventricular Fibrillation

Amplitude 0.5, 1.0, 1.5 and 2.0 mV.

e. Click the **Run** button. PRO-Soft will set the ECG wave and the amplitude and start waiting for a defibrillation. A defibrillation can then be fired until the **Stop** button is pushed.

If the **Test Pulse** button is activated while PRO-Soft is waiting for a defibrillation, the QA-40M/45 will generate a test pulse. The test pulse result will be shown in the form.

APEX (+) pad → right plate
STERNUM pad → left plate

f. Securely place the defibrillator paddles on the QA-40M/45 contact plates, and discharge the defibrillator. The APEX (+) pad should be connected to the right-hand plate, and the STERNUM pad to the left plate. This ensures correct signal polarity for the oscilloscope output. A reversal of this configuration will not damage the QA-40M/45, nor will it give incorrect energy readings. However, the polarity of the oscilloscope output will simply be reversed. The discharge from the defibrillator is transferred to the QA-40M/45's load resistance.

g. Following discharge PRO-Soft will display delivered energy, peak voltage, current, and synchronization delay in the upper right portion of the **Test Result** field. After ten seconds PRO-Soft also displays the discharge wave form in the lower right portion of the **Test Result** field.

h. Before changing ECG wave or amplitude, click the **Stop** button. Then enter setting changes.

i. Select **Close** to terminate testing and return to the Main Screen. To print a report select the **Print** button.

4.2 ECG Performance Test

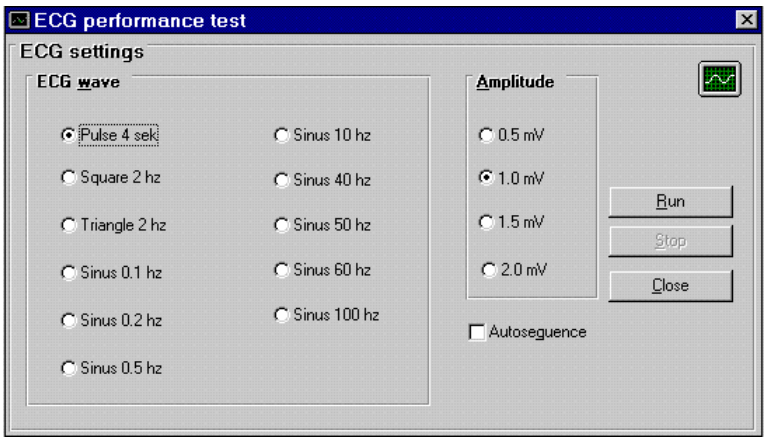
1. **General**. The ECG Performance Test simulates the following waves, and is designed for testing ECG monitors. Testing accuracy is ± 5 % (Lead II 1.0 mV).

Pulse:	1.0 mV Pulse lasts for 4 seconds. Used for testing low frequency responses.
Square:	2 Hz 1.0 mV p-p biphasic. Used for testing amplification and damping.
Triangle:	2 Hz 1.0 mV. Used for testing linearity.
Sinus:	0.1, 0.2, 0.5, 10, 40, 50, 60, and 100 Hz. Used for testing frequency response.
Amplitude:	0.5, 1.0, 1.5, 2.0 mV (Lead II)

2. **Test Procedure.**
   a. Initiate remoting. *(See chapter 3.)*
   b. Set the defibrillator to 'SYNCHRONIZED' mode, if desired. If set, there must be an ECG wave and amplitude to simulate before testing begins. While the test is activated, the waveform and amplitude cannot be changed.

   c. Press the **ECG Performance Test** icon button or select **QA-45, ECG performance test** from the PRO-

Soft QA-40M/45 Main Menu, and the following appears.



d. Select the desired **ECG wave** and **Amplitude** settings.

d. Click on the **Run** button. PRO-Soft runs the ECG performance wave until the **Stop** button is selected.

APEX (+) pad → right plate
STERNUM pad → left plate

d. Securely place the defibrillator paddles on the QA-40M/45 contact plates, and discharge the defibrillator. The APEX (+) pad should be connected to the right-hand plate, and the STERNUM pad to the left plate. This ensures correct signal polarity for the oscilloscope output. A reversal of this configuration will not damage the QA-40M/45, nor will it give incorrect energy readings. However, the polarity of the oscilloscope output will simply be reversed. The discharge from the defibrillator is transferred to the QA-40M/45's load resistance.

e. ECG performance waves can be run in sequence. By selecting **Autosequence**, a mark will appear in the checkbox. This mark tells you that if the **Run** button is pushed, PRO-Soft will run the chosen ECG for ten seconds before jumping to the next one. All ECG waves are performed in sequence.

If you do not want to wait ten seconds for the next wave, the **Advance** button may be used. By selecting this button the program will stop executing the active ECG wave and start running the next on the list. To select the previous wave in the list click the **Back** button.

f. Select **Close** to terminate testing and return to the Main Screen. To print a report select the **Print** button.

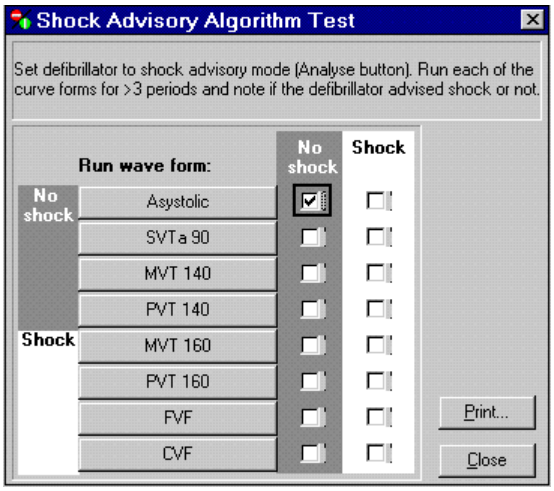
4.3 Shock Advisory Algorithm Test

1. **General**. This tests the analysis and prompting of certain defibrillators that can advise operators as to whether or not to perform a shock. PRO-Soft QA-40M/45 can simulate eight specific waveforms for analysis by the defibrillator that should then prompt the user to 'shock' or 'no shock,' in accordance with national and international guidelines. The waveforms are:

Asystolic:	No ECG	No shock
SVTa_90:	Supraventricular tachycardia, 90 BPM	No shock
PVT 140:	Monoventricular tachycardia, 140 BPM	No shock
MVT 140:	Polyventricular tachycardia, 140 BPM	No shock
PVT 160:	Monoventricular tachycardia, 160 BPM	Shock
MVT 160:	Polyventricular tachycardia, 160 BPM	Shock
CVF:	Coarse Ventricular Fibrillation	Shock
FVF:	Fine Ventricular Fibrillation	Shock

2. **Test Procedure**.
   a. Initiate remoting. *(See chapter 3 for more information)*

   b. Press the **Shock Advisory Algorithm Test** icon button or select **QA-45, Shock advisory algorithm_test** from the PRO-Soft QA-40M/45 Main Menu, and the following test window appears.



APEX (+) pad → right plate
STERNUM pad → left plate

   c. Securely place the defibrillator paddles on the QA-40M/45 contact plates, and discharge the defibrillator. The APEX (+) pad should be connected to the right-hand plate, and the STERNUM pad to the left plate. This ensures correct signal polarity for the oscilloscope output. A reversal of this configuration will not damage the QA-40M/45, nor will it give incorrect energy readings. However, the polarity of the oscilloscope out-

put will be reversed. The discharge from the defibrillator is transferred to the QA-40M/45's load resistance.

d. Set the defibrillator to 'SHOCK ADVISORY' mode.

e. Run each of the curve forms for three or more seconds.

f. Check the appropriate check box if the defibrillator advised 'shock' or 'not to shock.'

g. Select **Close** to terminate the test and return to the Main Screen. To print a report select the **Print** button.

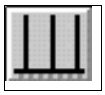
4.4 Pacemaker Accuracy Test (QA-45 Only)

1. **General**. This test evaluates the pacer frequency and delivered energy, and determines if noise interferes with the pacing. To conduct it, the operator selects the following parameters:

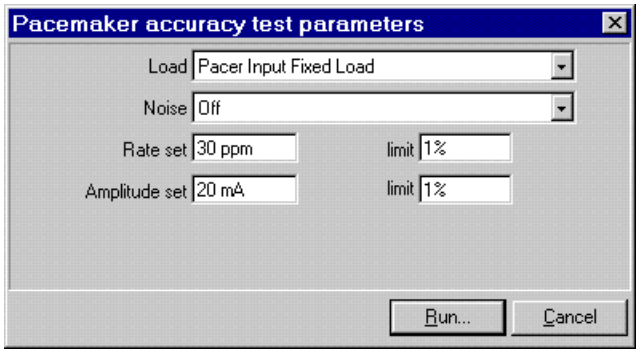
Load:	The load that will be applied between the pads. The options are Pacer Input Fixed Load, or load ranges of 50 to 2300 ohms. The latter are in steps of 50 ohms up to 200 ohms, and 100 ohms from 200 up to 2300 ohms.
Noise:	To simulate disturbances, 50 Hz, 1-10 mV or 60 Hz, 1-10 mV noise can be added
Rate set and limit:	This specifies the target rate in ppm, and the accepted deviance in percent.
Amplitude set:	This specifies the target amplitude in mA, and the accepted deviance in percent.

2. **Test Procedure**.

a. If testing with noise, set pacemaker to 'DEMAND' mode.



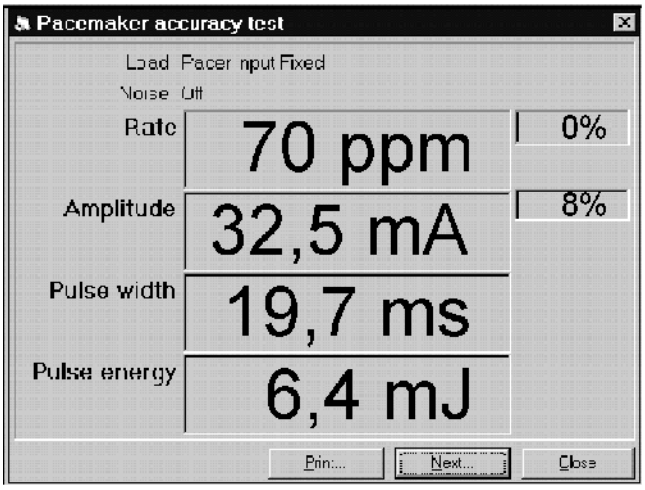
b. Press the **Pacemaker Accuracy Test** icon button or select **QA-45, Pacemaker accuracy test** from the PRO-Soft QA-40M/45 Main Menu, and the test setup window appears.



c. Enter the desired settings.

d. Click on the **Run** button. The test result window then appears *(see below)* displaying the rate, amplitude,

pulse width and energy. For the rate and amplitude it also shows the relative deviance (in percent) from the target settings.



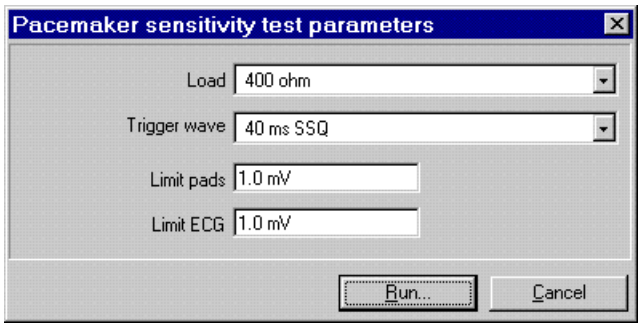
e. The result window continues to show the measurements until you click the **Close** button. To print a report select the **Print** button. If you want to make a new pacemaker accuracy test select the **Next** button to set test parameters.

4.5 Pacemaker Sensitivity Test (QA-45 Only)

1. **General.** Sensitivity is the minimum QRS amplitude (mV) required to cause the pacemaker to operate in the 'DEMAND' mode. During sensitivity measurement three different waveforms are selectable, with widths varying in steps from 10 to 200 ms. This waveform is delayed from the pacer pulse so that it is outside the pacing refractory period. PRO-Soft QA-45 then checks whether this wave is sensed or not by the pacemaker. If it is not sensed, a message 'EXCEEDED' is displayed, which means that the pacemaker needs an amplitude of more than 100 mV for sensing at that setting. If the wave is sensed, PRO-Soft then reduces the amplitude in steps until it reaches the lowest value required for the pacemaker to sense it. (The internal algorithm used converges to the lowest value in the least number of cycles.) This lowest value is the pace trigger sensitivity. Parameters to this test are:

Load:	The load that will be applied between the pads
Trigger wave:	The waveform that will be used to trigger the pacemaker. **NOTE:** A high pacer rate shortens the length of the test
Limit pads:	The maximum allowed threshold
Limit ECG:	The maximum allowed threshold

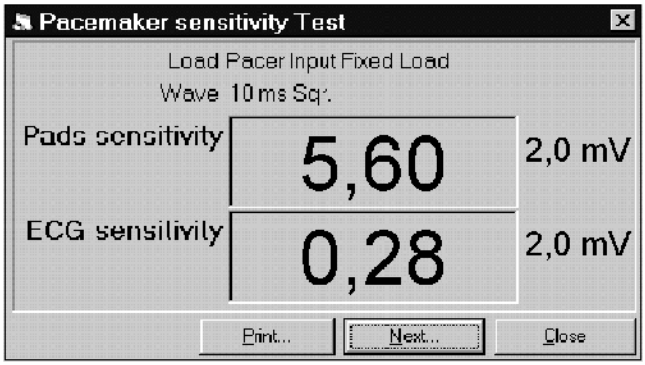
2. **Test Procedure.**
   a. Press the **Pacemaker Sensitivity Test** icon button or select **QA-45, Pacemaker sensitivity test** from the PRO-Soft QA-40M/45 Main Menu, and the test setup window appears.



   b. Enter the desired settings.

   c. Click on the **Run** button. The test takes approximately 40 seconds with a pacemaker setting of 120 ppm.

   b. The test result window then appears *(see below)* displaying the Pads and ECG sensitivity in ms, and amplitude in mV.



   c. The result window continues to show the measurements until you click the **Close** button. To print a report select the **Print** button. If you want to make a new pacemaker accuracy test select the **Next** button to set test parameters.

4.6 Pacemaker Refractory Period Test (QA-45 Only)

1. **General.** This test is used to test the time interval in milliseconds during which the pacemaker is insensitive to any external

inputs. PRO-Soft does this by measuring the maximum time interval after the generation of a pacer pulse, and maximum time interval after a QRS wave.

a. **Refractory Period**. A time interval in milliseconds, during which a pacemaker is insensitive to any external inputs. If a QRS is detected during this period, the pacemaker ignores it. On the other hand, if a QRS is detected outside the refractory interval, then the pacemaker resets its internal timer and the next pacer pulse is generated after a delay of one time period from this QRS wave.

b. **Paced Refractory Period.** The maximum time interval after the generation of a pacer pulse during which time the presence of a QRS wave is ignored.

   The measurement of paced refractory period takes a few cycles of the pacemaker output. First, PRO-Soft measures the pacer-to-pacer interval T. Then, it puts out a square wave 40 milliseconds wide, delayed by delay time D, which is more than the pacing refractory period, from the last pacer pulse. The pacemaker senses this square wave. The delay time D is gradually decremented in subsequent cycles until the square waveform is not sensed by the pacemaker. The maximum value of the delay time D, for which the pace maker does not sense the square wave, is the paced refractory period.

c. **Sensed Refractory Period.** The maximum time interval after a QRS wave is sensed by the pacemaker during which time the presence of a second QRS wave is ignored.

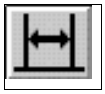
   The sensed refractory period is measured in a similar manner, except that PRO-Soft now generates two square waves instead of one. The first square wave is generated at a fixed time delay from a pacer pulse, which is greater than the paced refractory period. The pacemaker always senses this square wave.

   The second square wave is generated at a delay D from the first square wave. The initial value of D is selected to be greater than the sensed refractory period. Therefore the first time the pacemaker is on it also senses the second square wave. In subsequent cycles, the delay 'D' is gradually reduced until the pacemaker is unable to sense the second square wave. The maximum value of D, for which the pacemaker does not sense the second square wave, is the sensed refractory period. The purpose of the Pacemaker Refractory Period Test is to ensure that the pacer does not give pulse when the heart is in the refractory state (T wave).

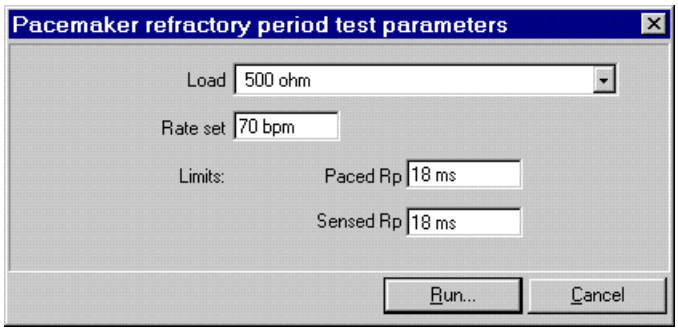
Parameters to this test are:

Load:	The load that will be applied between the pads
Rate set:	The rate at which the pacemaker is set. **NOTE:** A high pacer rate shortens the length of the test
Paced refractory period limit:	Specifies the minimum paced refractory period limit. **NOTE:** The limits are specified for each pacemaker, and depend on the pulse rate that is set in the pacemaker.

2. **Test Procedure.**



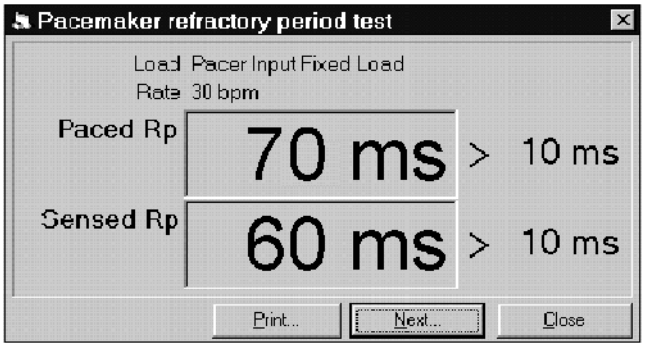
a. Press the **Pacemaker Refractory Period Test** icon button or select **QA-45, Pacemaker refractory period test** from the PRO-Soft QA-40M/45 Main Menu, and the test setup window appear.



b. Enter the desired settings.

c. Click on the **Run** button.

d. The test result window then appears *(see below)* displaying the paced and sensed refractory periods in milliseconds.

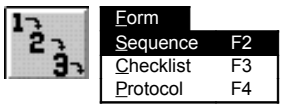


e. The result window continues to show the measurements until you click the **Close** button. To print a report select the **Print** button. If you want to make a new pacemaker accuracy test select the **Next** button to set test parameters.

5. Sequence Testing

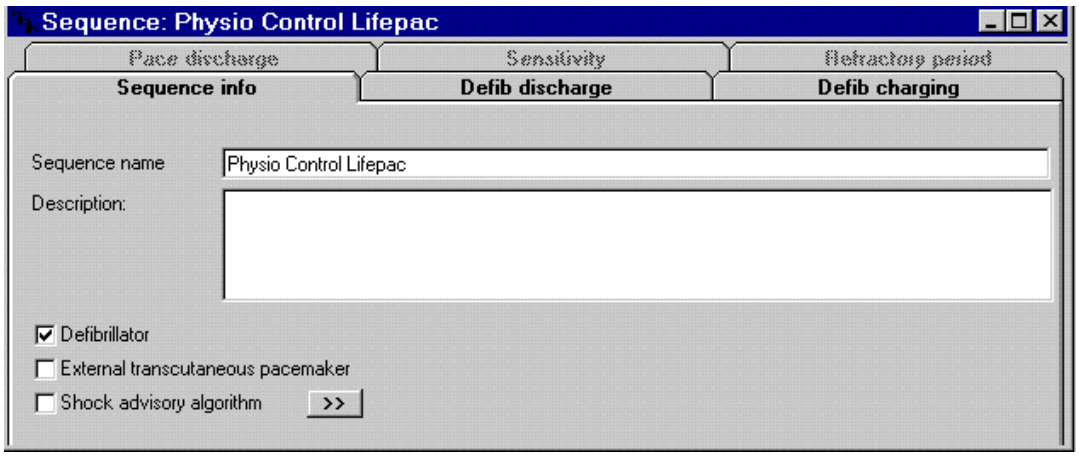
Sequence testing enables the operator to perform multiple tests semiautomatically. Instead of manually setting up and running one test at a time, a sequence of several tests can be set up in advance of testing. Once a sequence is created it can be it for later retrieval, and reuse. There are no restrictions on how the sequence is composed.

5.1 Sequence Form Window



Press the **Sequence** icon button from the icon menu bar, or select **Form, Sequence** from the PRO-Soft QA- 40M/45 Main Menu. The sequence window appears. The window contains six tabs. The **Sequence info** tab contains general information about the sequence, and has three control buttons with which to activate the tabs. Checking:

1. **Defibrillator** activates the tabs for:
   - Defibrillator Discharge Test
   - ECG Performance Test
2. **External transcutaneous pacemaker** activates the tabs for:
   - Pacemaker Discharge (Accuracy) Test
   - Pacemaker Sensitivity Test
   - Pacemaker Refractory Period Test
3. **Shock advisory algorithm** activates the window for the Shock Advisory Algorithm Test. *(See Chapter 4)*



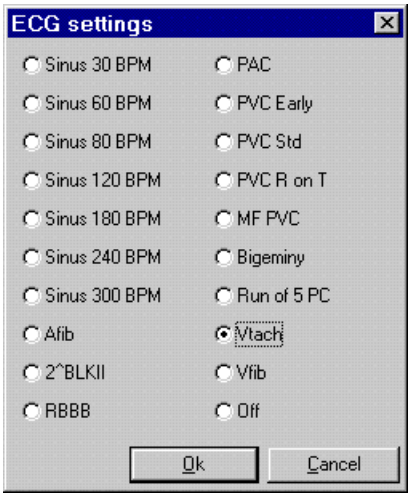
5.2 Defibrillator Test Sequence Setup

1. **General**. By clicking one of the defibrillator test tabs, the corresponding card will be displayed, containing a table for entering the settings to be incorporated in the testing.

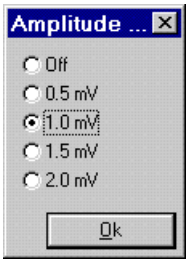
2. **Defibrillator Discharge Test**. This tab provides a table for entering configuration parameters as follows:

Set Energy (J)	Energy test value in joules
Limit (%)	Limit value for delivered energy in percent. **NOTE**: PRO-Soft allows to set illegal limit values (i.e., less than)% or greater than 100%). Therefore, enter only values between 0 -100%.
Max. Delay (ms)	If desired, the upper limit value for the delay, in milliseconds

If an ECG wave with an amplitude is desired for each test click, respectively, the **ECG** and **Ampl** fields. When the **ECG** field is clicked, the following window appears. Only the presets shown are available. Select the desired wave, then press **OK**. The preset will then be entered in the **ECG** field in the test table.



When the **Ampl** field is clicked, the following window appears. Select the desired amplitude, then press **OK**. The preset will then be entered in the **Ampl** field in the test table.



3. **Defibrillator Charging Test**. This tab provides a table for entering configuration parameters as follows:

Set Energy (J)	Energy test value in joules
Limit (%)	Limit value for delivered energy in percent. **NOTE**: PRO-Soft allows to set illegal limit values (i.e., less than)% or greater than 100%). Therefore, enter only values between 0 -100%.
Max. Delay (ms)	If desired, the upper limit value for the delay, in milliseconds

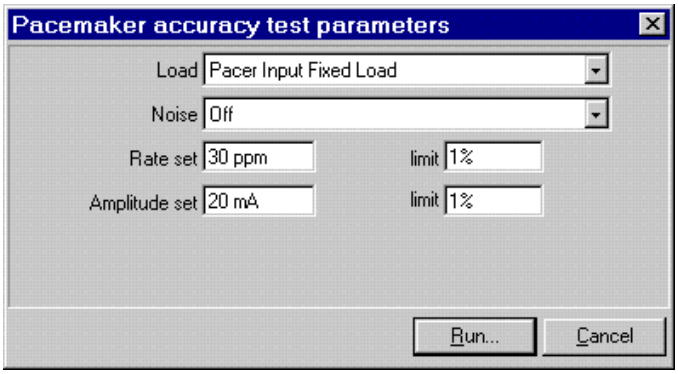
5.3 Pacemaker Test Sequence Setup

1. **General**. By clicking one of pacemaker test tabs, the corresponding card will be displayed, containing a table for entering the settings to be incorporated in the testing.

2. **Pace Discharge (Accuracy) Test**. This tab provides a table for entering the following configuration parameters:

Rate (ppm):	Target rate in ppm.
Amplitude (mA):	Target amplitude in mA.
Rate limit (%):	Accepted deviance in percent.
Amplitude limit (%):	Accepted deviance in percent.
Load:	The load that will be applied between the pads. The options are Pacer Input Fixed Load, or load ranges of 50 to 2300 ohms. The latter are in steps of 50 ohms up to 200 ohms, and 100 ohms from 200 up to 2300 ohms.
Noise:	To simulate disturbances, 50 Hz, 1-10 mV or 60 Hz, 1-10 mV noise can be added

When **any** field is clicked, the Pacemaker Accuracy Test Window appears.

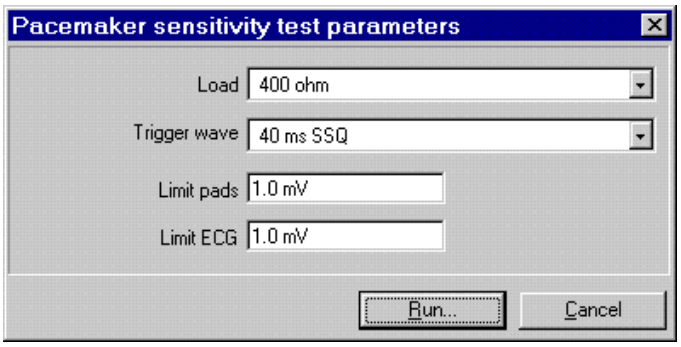


Enter either the values into the text boxes, or select from the drop down lists. When the desired values are entered, press **Run**. The configuration is then transferred to the Pace Discharge test tab.

3. **Sensitivity Test**. This tab provides a table for entering the following configuration parameters:

Limit pads (mV):	The maximum allowed threshold in mV
Limit ECG (mV):	The maximum allowed threshold in mV
Wave:	The waveform that will be used to trigger the pacemaker. **NOTE:** A high pacer rate shortens the length of the test
Load:	The load that will be applied between the pads

When **any** field is clicked, the Pacemaker sensitivity test parameters window appears.

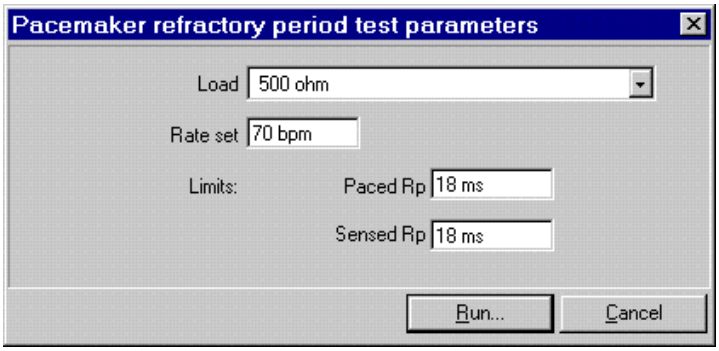


Enter either the values into the text boxes, or select from the drop down lists. When the desired values are entered, press **Run**. The configuration is then transferred to the Sensitivity test tab.

4. **Refractory Period Test**. This tab provides a table for entering the following configuration parameters:

Pacer rate (ppm):	The rate at which the pacemaker is set. **NOTE:** A high pacer rate shortens the length of the test
Limit paced (ms):	Minimum paced refractory period limit, in ms. **NOTE:** The limits are specified for each pacemaker, and depend on the pulse rate that is set in the pacemaker.
Limit sensed (ms):	Minimum sensed refractory period limit, in ms. **NOTE:** The limits are specified for each pacemaker, and depend on the pulse rate that is set in the pacemaker.

When **any** field is clicked, the following manual pacemaker refractory period parameters window appears.

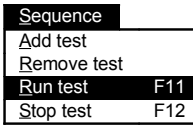


Enter either the values into the text boxes, or select from the drop down lists. When the desired values are entered, press **Run**. The configuration is then automatically entered in the sequence test tab.

5.4 Running a Sequence

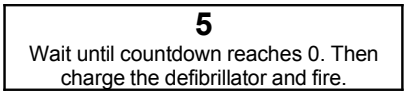
After a test sequence has been defined and saved, it can be retrieved and used at any time. To run a sequence test:

1. Load the test sequence desired by pressing the **Sequence** icon button or selecting **Form, Sequence**, or **Form, Protocol, View Sequence** from the PRO-Soft QA- 40M/45 Main Menu.
2. Select **File**, **Load sequence.** The **Browse** window opens, from which the desired test sequence can be opened. Either double-click a file to open it, or highlight it and press the **Open** button.
3. From the Sequence Menu select **Sequence**, **Run test**. The sequence will then start running in the following order:

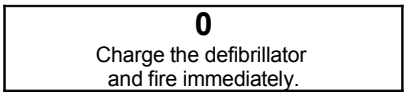


   - Defibrillator Discharge Test
   - Defibrillator Charging Test
   - Pacemaker Discharge Test (QA-45 Only)
   - Pacemaker Sensitivity Test (QA-45 Only)
   - Pacemaker Refractory Period Test (QA-45 Only)
   - Shock Advisory Algorithm Test *(if selected)*
4. In the Defibrillator Discharge Test, following discharge, PRO-Soft displays delivered energy, peak voltage, current, and synchronization delay for each test automatically. After ten seconds PRO-Soft also displays the discharge wave form in the lower portion of the test tab.

5. When the Defibrillator Charging Test tab opens press the Charge Timer (clock at the lower left of the tab). PRO-Soft counts five seconds after test start, showing the following window, with a red background, during the countdown:

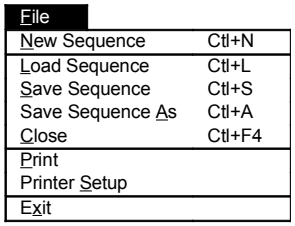


   When the countdown reaches zero, the window changes to green, and the following message appears:

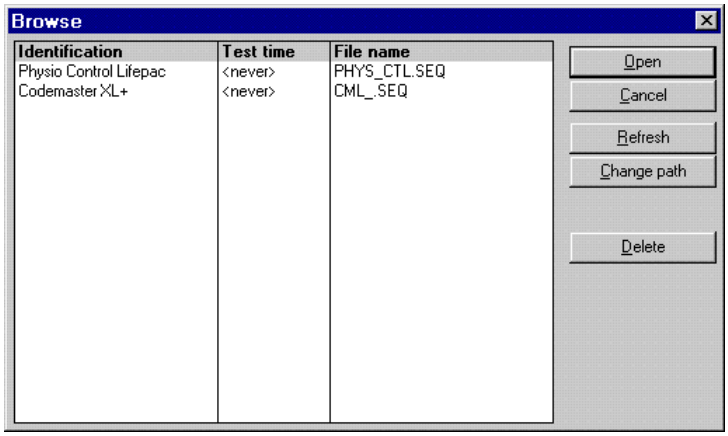


   Press charge, and then press discharge until the pulse is given. The test will then display the measured time from the end of countdown until the pulse is given, as well as the resultant energy.

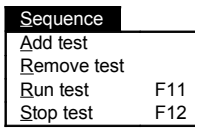
5.5 Sequence File Management



1. **New Sequence**. Creates a blank sequence form. If an existing sequence is in the form when this option is chosen, PRO-Soft QA-40M/45 will prompt the user as to whether or not the current sequence is to be saved before clearing the form.
2. **Load Sequence**. Opens the Browse form (*see below*) where a previously saved sequence can be retrieved. This is done by highlighting the sequence to be retrieved and pressing **Open**, or double-clicking the desired sequence. If an existing sequence is in the form when this option is chosen, PRO-Soft QA-40M/45 will prompt the user as to whether or not the current sequence is to be saved before loading the next sequence.



3. **Save Sequence** and **Save Sequence as**. Saves the current sequence in the Sequence Database under the current or new file name, as appropriate. By selecting the preferred storage format both the sequence setup and the sequence result can be saved. When saving test sequences the Browse form is opened, and you must specify a sequence name.



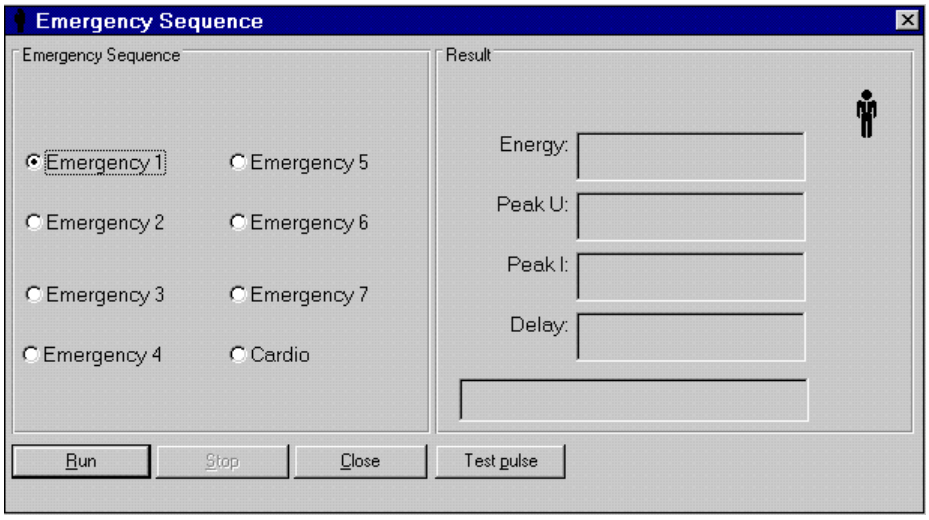
4. **Adding and Removing Tests**. New tests are added by selecting **Sequence, Add test, or Sequence, Remove test**.
5. **Print**. To print a protocol, select **File, Print**. Then select whether to print the protocol or write it to a file.

6. Emergency Sequence Training

A unique feature of PRO-Soft QA-40M/45 is its ability to make QA-40/45 serve as a training aid device for medical staff personnel who operate defibrillators in the course of their duties. Several ECG waveform emergency sequences are incorporated into the program. These sequences interact with incoming defibrillator pulses, simulating various patient cardiovascular conditions.

6.1 Sequence Setup

Emergency sequences can be activated in two ways. One is to select the **Emergency Sequence Test** icon button from the menu bar in the Main Application Window. The other method is to select **QA-45, Emergency sequence test** from the PRO-Soft QA-40M/45 Main Menu. In doing either, the **Emergency Sequence** window opens:



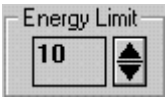
1. **Emergency Sequence**. This field has seven emergency sequences, and one cardioversion sequence from which to select.

SEQUENCE	PARAMETERS
Emergency 1	Starts with an 80 BPM normal sinus rhythm for 10 beats, a PVC (R on T), six normal beats, another PVC (R on T) and then goes to a continuous Vfib. Firing the defibrillator at any energy level will convert to normal ECG.
Emergency 2	Starts with 10 normal beats, then has 25 beats of Vtach, and then also goes to a continuous Vfib. Firing the defibrillator at any energy level will convert to normal ECG.
Emergency 3	Starts with Vfib. If a 200 Joule pulse is fired within two minutes of starting, the waveform converts to normal. Otherwise, the ECG will continue running

SEQUENCE	PARAMETERS
	Vfib.
Emergency 4	Same as Emergency 3, except that two pulses at 200 Joule are required within two minutes to convert to normal ECG.
Emergency 5	Same as Emergency 4, except that two pulses at 200 Joule followed by one pulse at 360 Joule are required within two minutes to convert to normal ECG.
Emergency 6	Same as Emergency 5, except that after converting to normal and beating normally for three minutes, the ECG shows two PVCs (R on T) and then reenters Vfib. The same series of two pulses at 200 J and one at 360 J are required within two minutes to convert to normal. Otherwise, the ECG will continue running Vfib.
Emergency 7	ECG waveform starts at Vtach at 180 BPM for one minute then goes to Vfib. Any defibrillator pulse within two minutes will convert to normal. Otherwise, the ECG will continue running Vfib.
Cardio	This sequence starts at continuous Atrial fibrillation. The <<patient>> must be defibrillated synchronously to be successful.

2. **Result**. Following discharge PRO-Soft displays delivered energy in joules, peak voltage in volts, current in amps, and synchronization delay in milliseconds, in this field.

6.2 Running Emergency Sequences 1 - 7



1. Select one of the emergency sequences. Emergency sequences 3 through 6 require a certain energy of defibrillation, or sequence of energies, to convert to a normal ECG waveform. In these sequences allowed variations must be specified. To do so, enter the variation in the field labeled **Energy Limit** (%) *(see illustration)*.
2. Click on the **Run** button. PRO-Soft will then start executing this sequence.
3. These sequences feature Vfib either immediately, or after running for a while. During execution, PRO-Soft displays text showing the active ECG wave.
4. Whenever the sequence is in a Vfib state, the system waits for a defibrillation. The measured energy, voltage, current and delay will be displayed in the **Result** field.
5. When the **Test pulse** button is clicked, QA-40M/45 substitutes the internal test pulse for an actual pulse, and assumes that the pulse is the correct energy for the current sequence.
6. Before changing emergency sequences, or to cardio sequence, click the **Stop** button.

NOTE
After a correct defibrillation, the ECG may continue running Vfib for a short time before converting to normal. This is not physiological, and is due to the speed of the communication between the QA-40M/45 and the PC.

7. Select **Close** to terminate the test and return to the Main Screen.

6.3 Running Cardio Sequence

1. Select **Cardio**. When selected the following additional control buttons appear in the window:

2. Click **Run**. PRO-Soft will then execute the sequence, starting at continuous Afib. The <<patient>> must be defibrillated synchronously to be successful.
3. Fire a real synchronized defibrillator into the load, or click on the **Sync** button to use a test pulse.
   a. If the defibrillator pulse comes within 120 ms of the ECG <<R>> wave, then the defibrillation is successful and the wave will convert to a normal ECG.
   b. If the defibrillator pulse is not synchronized within 120 ms, or if the **Late** button for a **Test pulse** is pushed, the waveform will show the progress of Vfib. The <<patient>> is then in an emergency condition, and a 200 joule pulse is required to convert the waveform to normal.
4. Before changing to an emergency sequence, click the **Stop** button.

7. Select Close to terminate the test and return to the Main Screen.

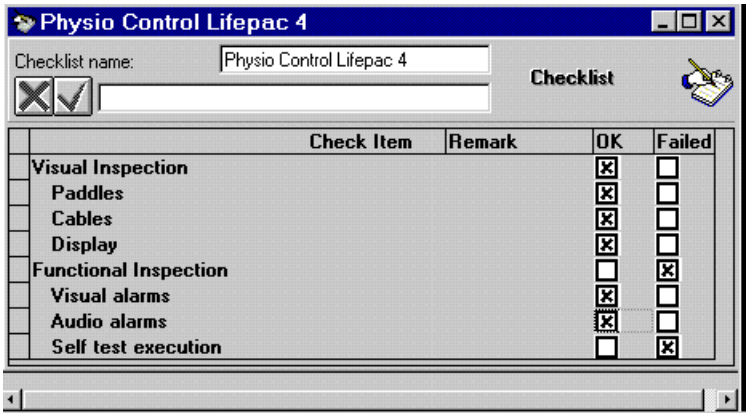
8. Checklists

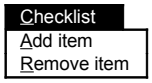
The checklist adds manually or visually performed tests and function checks to the protocols *(see Chapter 8)*. Once created, a checklist can be edited, stored and retrieved for future use.

8.1 Checklist Form Window

SequenceF2
ProtocolF4

Press the **Checklist** icon button from the icon menu bar, or select **Form, Checklist** from the PRO-Soft QA-40M/45 Main Menu and the Checklist form appears *(see below)*. It is a table allowing for up to 30 lines, where each line contains a description of what to examine (up to 50 characters). Each line also has two check boxes, 'OK' and 'Failed,' to be used when examining the defibrillator or transcutaneous pacemaker.

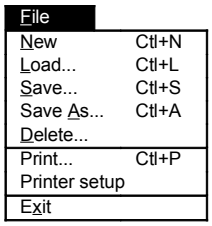




To enter text, or edit text highlight the field you want to edit with the mouse, and then enter the text. After entering the desired text either press ☑ to confirm the new or changed text, or ☒ to discard it. Another method is to select **Checklist**, then either **Add item** to create a new checklist item, or **Remove item** to discard it.

In order to update the check boxes the checklist must be connected to a protocol and edited through this protocol *(see the protocols connected checklist in the section Protocol)*.

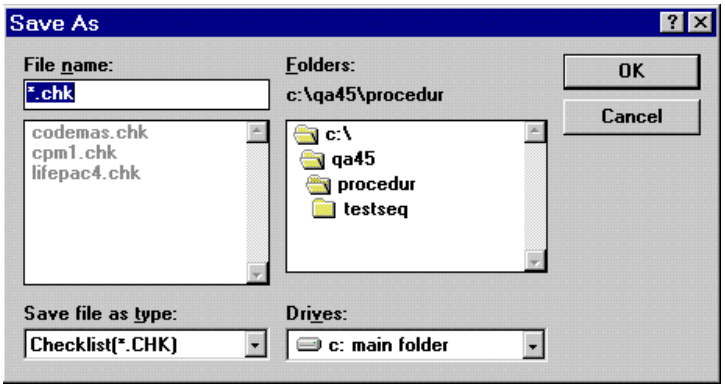
8.2 Checklist Files Management



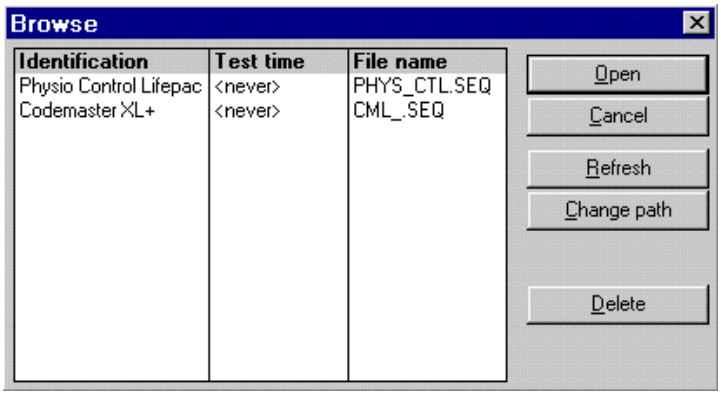
1. **New Checklist**. Select **File, New**. The current checklist window clears and initializes a new checklist form. If you already have an active checklist containing unsaved changes, a dialog box appears. It prompts you as to whether or not you want to save

the changes, discard them, or abort the operation and return to the active checklist.

2. **Loading and Saving Checklists**. To save the active checklist, select **File, Save** or **File, Save As**. A **Save As** window will open *(see below),* prompting for a name to use for the checklist. After the name has been entered in **File name**, press **OK**.



To retrieve an existing checklist, select **File, Load.** A **Browse** window opens *(see below).* Select among the available checklists and double click it, or highlight it and press **Open**.



3. **Printing Checklists**. To print a checklist, select **File, Print**. Then, select whether to print the checklist, or write it to a file.

9. Protocols

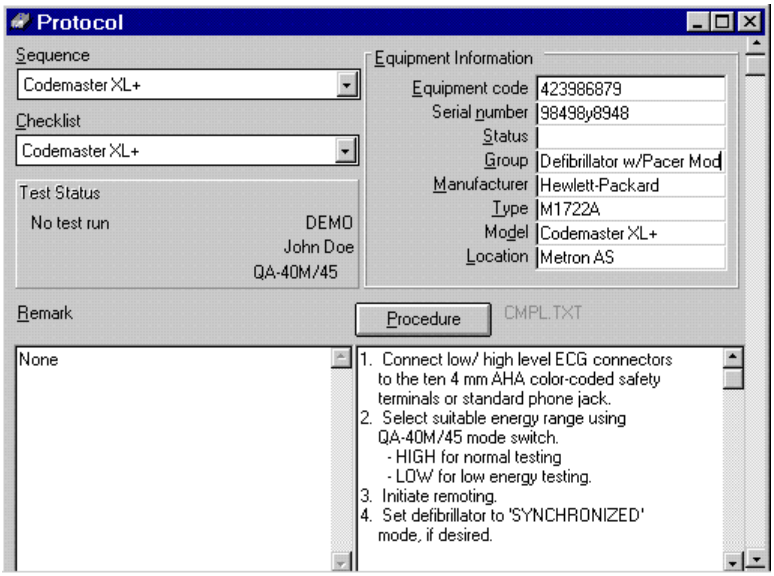
Protocol contains a description of the defibrillator or transcutaneous pacemaker being tested, and specifies an associated test sequence and checklist. It also includes a procedure file, stating special concerns for each defibrillator or pacemaker.

When saved, the results are added to PRO-Soft 40M/45's protocol database, or to QA-MAP, if installed. This database is an historical record of those protocols for which safety tests have been done with PRO-Soft. Information stored includes the:

- Tested defibrillator or pacemaker's identifying information.
- Test sequence used in the test
- Date the safety test was executed
- Status of the test (OK, Failed)
- Protocol filename containing the test results.

9.1 Protocol Form Window

Press the **Protocol** icon button from the icon menu bar, or select **Form, Protocol** from the PRO-Soft QA-40M/45 Main Menu and the Protocol form appears *(see below)*.



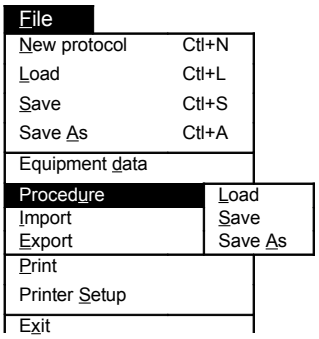
The Protocol application window contains the following fields:

1. **Equipment Information** Field. This field contains text boxes that are used to describe the defibrillator or transcutaneous pacemaker under test, and are also used in the safety testing report to document the test of a particular defibrillator or transcutaneous pacemaker. The text boxes, each containing space for up to 30 characters, are:

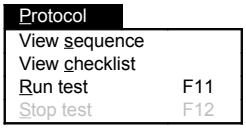
Equipment code:	The equipment identifier
Serial number:	The equipment serial number
Status:	The equipment status
Group:	The equipment group
Manufacturer:	Manufacturer of the equipment on test
Type:	The equipment type
Model:	The equipment model
Location:	Location of the equipment on test

   PRO-Soft can load equipment information already entered in an ASCII text file or, if you have PRO-Soft QA-MAP installed, from that program. *See paragraph 8.4.*

2. **Remark** Field. This field is for inserting remarks on the test. The remark may contain up to 300 characters long, describing special events that may have occurred during the testing. Any testing anomalies peculiar to the equipment under test, or on the testing itself, should be entered in this box.



3. **Procedure** Field. This field is for detailing the testing procedure used. For example, it can be a description of how to connect the QA-40M/45 to the instrument under test. Procedure is always saved to a separate text file (*.txt). It can be created and edited by typing the information in the procedure text box or, by using any text editor/word processor capable of saving plain text files (e.g., Windows Notepad). When you select an item in **File, Procedure**, a dialog box appears where you can specify the file you need by its filename. The title of the dialog box shown depends on whether you select **Load**, **Save** or **Save As**. If you have already saved the procedure, **Save** will store your changes under the filename you specified the first time you saved the file, while **Save As** will prompt you for a new filename.



4. **Sequence and Checklist** Fields. These drop down list boxes contain listings of all sequences and checklists resident in their respective databases. Select which of them PRO-Soft will use to test the equipment described in your protocol. When you have selected a sequence and checklist the menu items **Protocol**, **View sequence** and **Protocol**, **View checklist** become available. When selecting either of these menu items PRO-Soft will load the sequence or checklist and switch to the respective application window, where you may edit it before running the test. If you already have an active sequence or checklist, containing

unsaved changes, a dialog box appears, giving you an opportunity to save the changes.

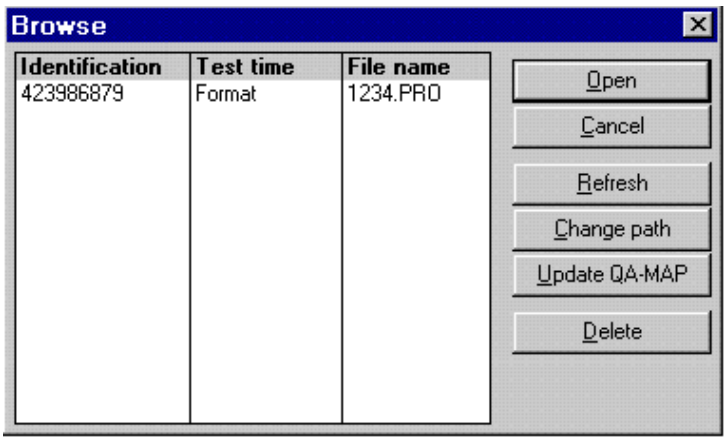
When first opening the protocol application window with a new protocol these fields will be blank, indicating that no sequence or checklist is connected to the protocol. They have to be created and connected to the protocol before they will appear.

9.2 Protocol Database

Protocols are saved and retrieved from the Protocol Database *(see below)*. This database is an historical record of those protocols for which safety tests have been done with PRO-Soft. The information stored includes the:

- Tested defibrillator or transcutaneous pacemaker's equipment code and serial number
- Test sequence used in the test
- Date the safety test was executed
- Status of the test (OK, Failed)
- Protocol filename containing the test results.

To access the protocol database the Protocol format must be open. To do so press the **Protocol** icon button from the icon menu bar, or select **Form, Protocol** from the PRO-Soft QA-40M/45 Main Menu. Then, select **File**, **Load**. The following dialog box appears:



The **Browse** window contains two fields.

1. **Identification/Test Time/File name**. These list boxes contain the protocols already added to the database by equipment serial number, test time and file name.
2. **Control**. This field manages the database.
   a. **Open** loads the selected protocol into the active protocol window, allowing you to view the safety test results and

other information stored in the protocol. If you already have a protocol open in the active window, and this protocol contains unsaved changes, PRO-Soft will not load the protocol selected in the database until you have responded to a dialog box prompting you to save the open protocol.

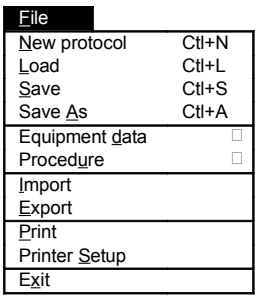
b. **Delete** removes selected protocol(s) from the library, prompting for confirmation. Clicking **No** prevents deletion. If more than one for deletion is selected, PRO-Soft will leave the current equipment and continue to the next one selected, and display the message for this one.

c. **Cancel** interrupts the entire delete operation. Note that equipment protocols deleted before selecting **Cancel** (or **No**) will not be restored.

d. **Update QA-MAP** is designed specifically to update METRON's QA-MAP. For this to operate QA-MAP must be installed, and the **QA-MAP** tab in **Options**, **Edit Options** must be configured accordingly *(see Chapter 2)*. When this button is clicked, PRO-Soft updates QA-MAP's **Test** table with the status of all test results added to the protocol database since the last update operation. Included in the update is the:

- Tested defibrillator or pacemaker's equipment code and serial number
- Test sequence used in the test
- Date the safety test was executed
- Status of the test (OK, Failed)
- PRO-Soft program executing the update (i.e., PRO-Soft QA-40M/45)

9.3 Protocol File Management



1. **New Protocol**. Select **File, New protocol**. The system will display an empty Protocol Form window. Fill in the required information and select the test sequence and checklist to use with the defibrillator or transcutaneous pacemaker being tested.

You can open multiple protocols to allow you to compare, for example, this year's and last year's test results. To do so select **Form**, **Protocol**, and then open another protocol window by selecting **File, New Protocol**. Then, select **Window, Tile Horizontal**, so that both forms appear together. To compare the test results load the protocol corresponding to this year's testing into one of the protocol windows, and the protocol corresponding the last year's testing into the other window.

2. **Saving Protocols**. Protocols are saved to the **Protocol Database**. To save the active protocol, select **File, Save** or **File,**

Save As. The Protocol Database window will open, and you will then be prompted for a name to use for the protocol.

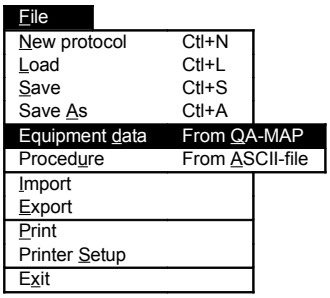
3. **Retrieving Protocols**. Select **File, Load**, and the **Browse** window is opened. Select among the available protocols the one that is desired, and double click to load it into the protocol window.

4. **Printing Protocols**. To print a protocol, select **File, Print.** Then, select whether to print the protocol or write it to a file.

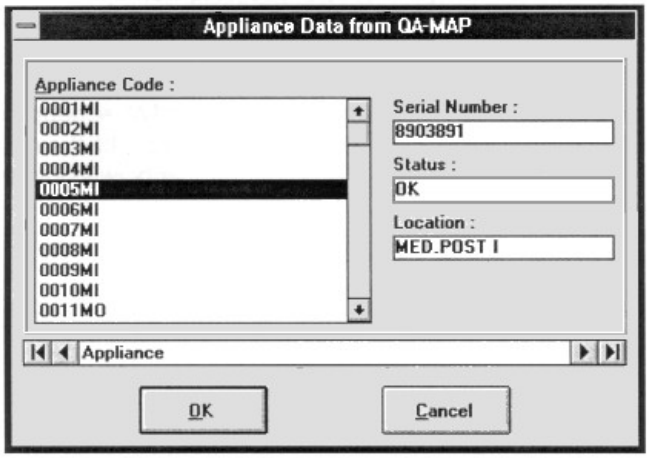
9.4 Importing Data

Equipment files pertaining to defibrillator or transcutaneous pacemakers in the inventory can be created from ASCII text files, or can be imported into PRO-Soft QA-40M/45 from METRON's QA-MAP program. This appendix details the procedures for these options.

1. **Retrieving from QA-MAP**. Data on the defibrillator or transcutaneous pacemaker to be tested can be imported directly from METRON's QA-MAP. For this feature to operate QA-MAP must be installed, and the **QA-MAP** tab in **Options**, **Edit Options** must be configured to reflect **Retrieve Appliance Data**. *(cf. Paragraph 2.2.2)*.

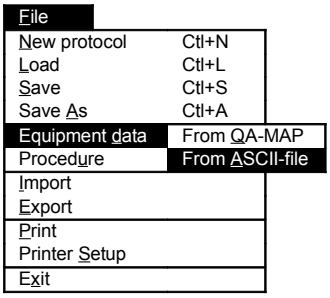


To import the data select **File, Equipment data, From QA-MAP** in the Main Menu.. When the following dialogue box appears, select the appliance code for the defibrillator or transcutaneous pacemaker you wish to test and click on **OK**. Information stored in QA-MAP states which test sequence to use for each defibrillator or transcutaneous pacemaker.



2. **Making Protocol Formats from an ASCII Text File**. PRO-Soft can load equipment information from an ASCII text file. ASCII text files can be created on each of the defibrillator or transcutaneous pacemakers for which you intend to produce protocol formats. The ASCII file must follow this pattern :

```
EquipCode       =   <Equipment Code>
SerNo           =   <Serial Number>
Status          =   <Status>
Group           =   <Group>
Manufacturer    =   <Manufacturer>
Model           =   <Model>
Type            =   <Type>
Location        =   <Location>
Sequence Name   =   <Name of Test Sequence>
Procedure       =   <Procedure Filename>
```



This file contains information on one defibrillator or transcutaneous pacemaker. The text preceding the '=' sign is only for your convenience. The text following the '=' sign is used to construct a protocol format. Make sure that the lines appear in the right order, i.e., appliance code first, ... , procedure text last. Use a text editor or a word processor that can save ASCII text to create the file (e.g., Notepad). To produce protocol formats from the data in the file, select **File, Equipment data, From** ASCII**-file**. Select the file containing the defibrillator or transcutaneous pacemaker information and click on **OK**. The program will read the file and add one new protocol format to the database library for each defibrillator or transcutaneous pacemaker

10. Troubleshooting

Problem	*Possible Solution*
Test sequence grid will not accept data	Check the tests to be made in the 'Tests' frame.
Reports are not printed	1. Wrong printer driver. Choose the correct printer when running print report. 2. Do not check the print to file box when running print report.
Strange characters appear in a report	Wrong printer driver. Choose the appropriate printer in the Print Manager program.
Ball does not rotate when remoting is attempted, or is set. Messages: 'The port is already taken (8005)' 'Error in Send Command at line 0. Operator valid only when port is open (8018).'	Communications are not established between the computer and the QA-IDS. Check to ensure that: 1. The QA-IDS is set to "Remote Control." 2. The correct COM-Port is assigned in the Options Menu. 3. The RS-232 cable has a null modem/data transfer configuration.

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APPENDIX A: ERROR REPORT FORM, PRO-SOFT QA-40M/45

PRO-SOFT QA-40M/45ERROR REPORT FORM

USA
1345 Monroe NW, Suite 255A
Grand Rapids, MI 49505
Phone: (+1) 888 863-8766
Fax: (+1) 616 454-3350
E-mail: *metronus@aol.com*

FRANCE
30, rue Paul Claudel
91000 Evry, France
Phone: (+33) 1 6078 8899
Fax: (+33) 1 6078 6839
E-mail: *metronfrance@infonie.fr*

NORWAY
Travbaneveien 1
N-7044 Trondheim, Norway
Phone: (+47) 7382 8500
Fax: (+47) 7391 7009
E-mail: *support@metron.no*

METRON

From: (name) Address:	Phone: Fax: Date:
PRO-Soft QA-40M/45 Error Report	Product: Version:

Type

☐ Wrong results	☐ Error messages, without reason
☐ Program stops, no reaction	☐ Wrong responses on commands.
☐ Other	

Description of the situation prior to the error:

Description of the error:

(METRON use internally)

Received date:	Comments:	☐ Critical
Correction date:		☐ Minor
Ref No.		☐ Normal

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APPENDIX B: SUGGESTION FORM, PRO-SOFT QA-40M/45

PRO-SOFT QA-40M/45 SUGGESTION FORM

USA
1345 Monroe NW, Suite 255A
Grand Rapids, MI 49505
Phone: (+1) 888 863-8766
Fax: (+1) 616 454-3350
E-mail: *metronus@aol.com*

FRANCE
30, rue Paul Claudel
91000 Evry, France
Phone: (+33) 1 6078 8899
Fax: (+33) 1 6078 6839
E-mail: *metronfrance@infonie.fr*

NORWAY
Travbaneveien 1
N-7044 Trondheim, Norway
Phone: (+47) 7382 8500
Fax: (+47) 7391 7009
E-mail: *support@metron.no*

METRON

From: (name) Address:	Phone: Fax: Date:
PRO-Soft QA-40M/45 Improvement Suggestion	Product: Version:

Type

☐ One window	☐ Presentation
☐ Several windows	☐ Options, configuration possibilities
☐ Documentation	☐ Other

Description of the suggested improvement:

(METRON use internally)

Received date:	Comments:
Correction date:	
Ref No.	

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